



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,796	08/13/2001	Margaret A. Schwarz	9022.8CT	8406

20792 7590 05/19/2004

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER

SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
----------	--------------

1635

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/928,796

Applicant(s)

SCHWARZ ET AL.

Examiner

J. Douglas Schultz

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-16 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 7-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-16 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/19/2003 4N0
8/13/2001
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Specification

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The oath contains a reference to U.S. Application Number 09/439,616, which has issued as U. S. Patent Number 6,306,612, which is not recited in the first sentence of the specification. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Election/Restrictions

2. Applicant's election with traverse of Group VIII in the Paper filed January 13, 2004 is acknowledged. The traversal is on the ground(s) that no evidence has been provided that it would be a serious burden to examine the claims of Groups IV-VIII claims together. Applicants note that Group IV and V are classified in class 435 subclass 7.1, and that Group VI, VII, and VIII are classified in class 435, subclass 6, and suggest that this provides evidence that no search burden is required. Applicants thus request reconsideration of examining Groups IV, V, VI and VII along with elected Group VIII.

This is not found persuasive because the mere fact that some of the Groups are in the same subclass is not considered to be good evidence that no search burden is required. For

Art Unit: 1635

example, in class 435, subclass 6, there are approximately 20,200 patents issued. In class 435 subclass 7.1, there are approximately 7,500 hundred patent issued. Thus it would require sifting through the claims of 27, 700 patents to find several distinct inventions, which is considered an undue burden. The requirement is still deemed proper and is therefore made FINAL.

Claims 7-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed January 13, 2004.

Claim Objections

3. Claim 10 is objected to because of the following informalities: the first occurrence of the word "probe" requires an "a" in front of it. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 recites the "The method of screening for ...". There is insufficient antecedent basis for use of the term "the" because the claim does not refer back to any other method. Substitution of the term "A" in place of "The" would be remedial.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or

Art Unit: 1635

with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-16 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The subject matter of the instantly claimed invention is drawn to methods of screening for compound useful for facilitating vascular growth in a subject, comprising screening for compounds that inhibit expression of EMAP II.

At the outset it is noted that the rejected claims do not recite any sequence identifier. The gene is thus considered to be defined and claimed by its function (i.e. that which is EMAP II-like) rather than by any specific or particular structure(s). Accordingly such language is broadly interpreted to embrace any sequence of any EMAP II, or any such molecule with analogous EMAP II activity, known or yet to be discovered, along with any isoform or allele present within any species, or any variant that is within reasonable similarity from this family of proteins that retain EMAP II function.

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Thus, an applicant complies with the written-description requirement by describing the invention, with all its claimed limitations, and by using such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention. To provide adequate written

Art Unit: 1635

description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical, structure/function correlation, methods of making the claimed product, and any combination thereof. The representative sample requirement may be satisfied by supplying structural or functional information, or a combination of both, such that one of skill in the art would be satisfied that applicants were in possession of the genus as claimed. Further, the size of the representative sample required is an inverse function of the unpredictability of the art.

The specification refers to an EMAP II isoform as taught by Stern (U. S. Patent Number 5,641,867), and appears to incorporate the disclosure of Stern by reference at page 6 line 25. However, no other EMAP II isoform of any other type is referenced in the specification, and the prior art does not appear to teach any further EMAP II. Furthermore, applicants specification does not recite the actual sequence of the EMAP II, but rather indicates its teaching in the Stern patent. The reference to only one sequence of EMAP II as taught by another person and not disclosed herein is not considered to meet the requirements for disclosure of a representative sample of structures that correlate to the genus of any molecule encompassing any EMAP II activity, such that one of skill would consider applicants to be in possession of said genus.

This is particularly true in view of the lack of any teaching that would assist one of skill in understanding the specific structure(s) that distinguish EMAP II function from non-EMAP II function. One of skill would not recognize from the specification that applicants were in possession of the instantly claimed EMAP II because nothing in the specification provides any teaching by way of structure what it is that provides for EMAP II activity. Thus, because the

Art Unit: 1635

distinguishing characteristics of the claimed genus are not described, claims to using the genus essentially amount to an invitation to experimentation to find other EMAP II sequences, because one of skill in the art would not be apprised as what structural features of EMAP II provide for its functional characteristics.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 571-272-0763.

The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James Douglas Schultz, PhD


SEAN McGARRY
PRIMARY EXAMINER
1635